

12093084

Rolence Enterprise Inc.
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5. 510(K) SUMMARY

DEC 1 6 2009

ROLENCE Dental High Speed Handpiece, Model: RHP

510K:

- Submitted by: **ROLENCE Enterprise Inc.**
No.18-3, Lane 231, Pu Chung Rd., Chungli, 32083,
Taiwan, ROC
- Contact person: Dr. Jen, Ke-Min
No.58, Fu-Chiun Street, Hsin-Chu City, 30067,
Taiwan, ROC
Tel: 886-3-5208829 fax: 886-3-5209783
E-mail: ceirs.jen@msa.hinet.net
- Date Summary Prepared: September 18, 2009
- Name of the Device: Dental Air-Powered Handpiece
- Classification: Dental Air-Powered Handpiece (class I medical
device; 21 CFR 872.4200)
Product code: EFB
Panel: 72
- Proprietary name: ROLENCE Dental High Speed Handpiece, model RHP
 - Predicate Device: JINDELL High Speed Air Turbine Handpiece,
models: SW, SP, SU, ETU, MU; 510K No – K062740
 - Statement of Intended Use: The ROLENCE Dental High Speed Handpiece,
model RHP is intended for removing carious
material, reducing hard tooth structure, cavity
preparation, finishing tooth preparations and
restorations and polishing teeth.



CAUTION: U.S. Federal law restricts the use of
this device to licensed professionals.

- Description of Device Design: According to ISO7785-1:1997, Dental Handpiece -- Part 1: High-speed air turbine handpieces; and ISO13485:2003, Medical Device Quality Management System to complete the device design steps.
- Risks Analysis Method: According to ISO14971:2007, we completed the Risks Management Report for the ROLENCE Dental High Speed Handpiece.
- Performance Data: The claim of substantial equivalence is based on comparisons of formulations and intended uses of the ROLENCE Dental High Speed Handpiece, model RHP and its claimed predicate.
And we also refer to the ISO7785-1 to verify the function test for the ROLENCE Dental High Speed Handpiece.
- Conclusion: Based on the information in the notification, ROLENCE Enterprise Inc. believes that the Dental High Speed Handpiece is substantially equivalent to the claimed predicate JINDELL High Speed Air Turbine Handpiece, models: SW, SP, SU, ETU, MU, 510K No. K062740.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

ROLENCE Enterprise Incorporated
C/O Mr. Shu-Chen Cheng
ROC Chinese-European Industry Research Society
2064 Tamarin Drive
Columbus, Ohio 43235

DEC 16 2009

Re: K093084
Trade/Device Name: Rolence Dental High Speed Handpiece Model RHP
Regulation Number: 21CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: September 20, 2009
Received: October 1, 2009

Dear Mr. Cheng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for" followed by a stylized signature.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health


Indications for Use

510 (K) Number (If Known): K 093084

- Device Name: ROLENCE Dental High Speed Handpiece, Model: RHP

Indications for Use :

- *ROLENCE Dental High Speed Handpiece, model: RHP is intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.*
- *ROLENCE Dental High Speed Handpiece carries the following label:*

 **CAUTION:** *U.S. Federal law restricts the use of this device to licensed professionals.*

Prescription Use ✓

AND/OR

Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Muly for MSR
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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